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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/383,054 | 08/25/99 | EDWARDS | D AIR-108PA |

HM12/0426
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| EXAMINER | |
|------------|--------------|
| PULLIAM, A | |
| ART UNIT | PAPER NUMBER |

1615

DATE MAILED: 04/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/383,054

Applicant(s)

EDWARDS ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
- ☐ received.
 - ☐ received in Application No. (Series Code / Serial Number) _____.
 - ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

Receipt is acknowledged of the Declaration, Filing Fee, and Surcharge, received November 1, 1999, as well as the Information Disclosure Statement, received February 28, 2000.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13-18, 22-34, 38-42, and 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/16882 to Durrani *et al.*. Durrani *et al.* disclose a process to directly spray dry a drug/ lipid powder composition comprising preparing an aqueous solution containing a drug and a lipid containing ethanol solution. The mixture is then spray dried to get particles (page 40, claim 1). Durrani *et al.* further teach that the drug may be selected from a group which includes insulin, granulocyte colony stimulating factor, interferons, growth factors, calcitonin, and interleukins (page 40, claim 2), as well as peptide hormones, and lung surfactant proteins (p 10-11). Durrani *et al.* further teach that the lipid may selected from the group consisting of phosphatidylglycerol, phosphatidylcholine, phosphatidylinositol, phosphatidylethanoamines, and

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phosphatidylserine (page 41, claim 4). Lastly, Durrani *et al.* teach that the diameter of the resulting particles is between 0.1 and 20 microns (page 14, line 30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/16882 to Durrani *et al.* as applied to claims 1-9, 13-18, 22-34, 38-42, and 46-49 above. Durrani *et al.* do not disclose the percent protein integrity or the tap density of the spray dried particles. However, based on the fact that Durrani *et al.* disclose the same components in the spray dried particles, it is the position of the examiner that the protein integrity and tap density are inherent characteristics, and would be the same as those claimed by applicant, absent the presentation of some unusual and/ or unexpected results. Further, on page 8 of the specification, applicant states that spray dried particles which have decreased stability are those without a phospholipid or with just an aqueous solvent. Durrani *et al.* teach the inclusion of phospholipids and organic solvents in their particles, so therefore, their particles would have the improved characteristics as claimed by applicant.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Pulliam, whose telephone number is (703) 308-4710. The examiner can normally be reached Monday to Friday from 7:30 am to 4:00 pm.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-1234.


THURMAN K. PAGE
SUPERVISOR PATENT EXAMINER
TECHNOLOGY CENTER 1600